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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,295	02/23/2006	Marie-Anne Petit	0508-1140	2042

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EXAMINER
BOESEN, AGNIESZKA

ART UNIT	PAPER NUMBER
1648	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/550,295	PETIT ET AL.	
	Examiner	Art Unit	
	Agnieszka Boesen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *35-68* is/are pending in the application.

4a) Of the above claim(s) *49,50,52-63 and 66-68* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *35-48,51,64 and 65* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/21/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Non-Final Office Action is responsive to the communication received December 31, 2007.

Election/Restrictions

Applicant's election with traverse of group I, claims 35-48, 51, 64, and 65 is acknowledged. Claims 49, 50, 52-63, and 66-68 are withdrawn because the claims are drawn to the non-elected invention.

Applicant argues that the immunogenic region recognized by Bartosch's antibodies is different from the immunogenic region recognized by the antibodies of the present invention and therefore Bartosch et al. fails to satisfy the requirements of PCT Rules 13.1 and 13.2.

In response to Applicant's arguments it is noted that Bartosch et al. broadly disclose antibodies binding to E1 and E2 HCV proteins, thus it is considered that Bartosch et al. disclose the special technical feature of the present invention. Applicants are reminded that unity of invention is considered with regard to the independent claims. Claim 35 require only that the antibody bind to the HCV envelope. Additionally, the reference by Foung et al. (WO 02/057314 A2) cited in the art rejection below discloses anti-HCV antibodies binding to the same immunogenic regions within E2 protein as the antibodies of the present invention. Thus Foung et al. disclose the special technical feature of the present invention. Therefore the restriction requirement is deemed proper and is made FINAL. Claims 35-48, 51, 64 and 65 are under examination in the present Office Action.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on September 21, 2005 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the Examiner.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 35-43 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims are drawn to a conformational antibody capable of specifically binding to the natural HCV viral envelope. Claims are rejected because the claims do not define over the naturally generated anti-HCV viral envelope antibodies as they are found in nature. For example the antibodies generated in a human infected with HCV read on the claimed antibodies. The recitation of "conformational" antibody is interpreted to refer to a conformational epitope antigen to which an antibody typically binds. A conformational anti-HCV envelope antibody would be typically generated in an HCV infected subject. Thus the recitation of "conformational" antibody does not define the present antibodies as different from those found in nature. Therefore the claims are rejected as being drawn to non-statutory subject matter.

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Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 44-47 and 51 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims are drawn to a monoclonal antibodies and hybridomas making the monoclonal antibodies deposited under accession number CNCN I-2983 and CNCM I-2982.

If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants, or statement by an attorney of record over his or her signature and registration number, stating that the instant invention will be irrevocably and without restriction released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein. If a deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809 and MPEP 2402-2411.05, Applicant may provide assurance of compliance by affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that:

(a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years. Or 5 years after the last request for the enforceable life of the patent, whichever is longer;

(d) a test of the viability of the biological material at the time of deposit (see CFR 1.807); and

(e) the deposit will be replaced if it should ever become inviable.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 35-40, and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Cocquerel et al. (Journal of Virology, January 2003, Vol. 77, p. 1604-1609 in IDS of 9/21/2005).

Claims are drawn to a conformational monoclonal antibody capable of specifically binding to the natural HCV viral envelope. The antibody is capable of precipitating the HCV E1E2 complex under of a non covalent form. Claims are drawn to an antibody that binds to the natural HCV E1 protein.

Cocquerel et al. disclose a conformational monoclonal antibody binding to the E2 HCV viral envelope protein and capable of precipitating the HCV E1E2 complex of a non covalent form (see the entire document, particularly Figures 1-4, and page 1605). Cocquerel et al. disclose a monoclonal antibody that binds to the natural HCV E1 protein (see Figure 1 and Figure description).

Thus by this disclosure Cocquerel et al. anticipate the present claims.

Claims 35-41, 43, and 48 are rejected under 35 U.S.C. 102(b) as being anticipated by Foung et al. (WO 02/057314 A2).

Claims are drawn to a conformational monoclonal antibody capable of specifically binding to the natural HCV viral envelope and a pharmaceutical composition comprising the anti-HCV antibodies and a pharmaceutically acceptable vehicle. The antibody is capable of precipitating the HCV E1E2 complex of a non covalent form. Claims are drawn to an antibody that binds to the natural HCV E1 protein. The conformational antibody binds an epitope constituted of at least one of epitopes: E1 (aa 297-206), E2 (aa 480-494) and E2 (aa 613-621).

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It is noted that the claims require that the antibody binds at least one epitope, thus the claims are anticipated by an antibody that binds one of the claimed epitopes.

Foung et al. disclose a monoclonal antibody binding a conformational epitope of E1 protein of HCV (see claim 2). Foung et al. disclose a monoclonal antibody binding conformational epitopes spanning the amino acids 470 trough 644 of E2 protein (see claims 9 and 10). The epitope disclose by Foung comprises the present epitopes E2 (aa 480-494) and E2 (aa 613-621). Thus Foung's antibody binds the E2 (aa 480-494) and E2 (aa 613-621) epitopes of the present invention. Sequence search analysis of SEQ ID NO: 3 recited in the present claims reveals that the amino acids 613-621 of the E2 (SEQ ID NO: 3) are identical with the amino acids of the E2 epitope disclosed in the prior art (see sequence comparison below, note that the Query represents amino acids 613-621 of the E2 SEQ ID NO: 3, and the Db represents SEQ ID NO: 192AA of Foung).

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Qy          XXXXXXXXXXXXXXXXXXXXYRLWHYPCTXXXXXXXXXXXXXXXXXXXX
            :::::::::::::::::::::|||||||||:::::::::::::::::::::
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Db TYTKCGSGPWLTPRCIVDYP**YRLWHYPCT**VNFTIFKVRMYVGGMEHRLN

Foung et al. disclose a pharmaceutical composition comprising the antibody specifically binding to the natural HCV viral envelope and a pharmaceutically acceptable vehicle (see claim 29).

It is noted that the functional limitations recited in the present claims with regard to the antibody being capable of precipitating the HCV E1E2 complex and neutralizing the HCV infections in patients, the limitations are considered to be an inherent property of the antibodies disclosed in the prior art. Because Foung's antibodies bind epitopes within the E2 protein, these antibodies are expected to precipitate the E1E2 complex and to neutralize the HCV infections in patients.

Thus Foung et al. anticipate the present claims.

Claims 64 and 65 are rejected under 35 U.S.C. 102(b) as being anticipated by Lechmann et al. (Hepatology, 2001, Vol. 34, p. 417-423).

Claims are drawn to a process for preparing a monoclonal antibody capable of binding to natural HCV viral envelope comprising immunizing an animal with a composition of HCV viral particles and selecting monoclonal antibodies that bind to the HCV viral particles.

Lechmann et al. disclose methods for preparing monoclonal antibodies binding to HCV E2 envelope comprising immunizing an animal with a composition of HCV viral particles and selecting monoclonal antibodies that bind to the HCV viral particles (see Materials and Methods).

Thus by this disclosure Lechmann et al. anticipate the present claims.

Conclusion

No claims are allowed.

Claim 42 is free of prior art of record. Claim 42 is interpreted to require that the conformational antibody of the invention binds all three epitopes E1 (aa 297-206), E2 (aa 480-494) and E2 (aa 613-621) together. The prior art of record discloses an anti-HCV antibody that binds to the two of the three epitopes E2 (aa 480-494) and E2 (aa 613-621) as discussed above (see rejection under 35 U.S.C. 102(b) as being anticipated by Foung et al.). The prior art does not disclose or suggest an anti-HCV antibody that binds all three epitopes together as required by the claims. In fact the above cited reference by Cocquerel et al. (Journal of Virology, January 2003, Vol. 77, p. 1604-1609) discloses an antibody that can precipitate the E2E1 complex however the reference teaches that the antibody only binds to the epitopes within E2 protein but not the epitopes within E1. Cocquerel et al. discloses another antibody that binds to E1, however this antibody is not the same as the antibody that binds E2. Thus the prior art antibody does not bind all three epitopes together.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnieszka Boesen whose telephone number is 571-272-8035. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Agnieszka Boesen, Ph.D./
Examiner, Art Unit 1648

/Bruce Campell/

Supervisory Patent Examiner, Art Unit 1648